Medical Policy

**Electrical Bone Growth Stimulation of the Appendicular Skeleton**

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**Policy Number:** 499
BCBSA Reference Number: 7.01.07
NCD/LCD: Local Coverage Determination (LCD): Osteogenesis Stimulators (L33796)

**Related Policies**
- Ultrasound Accelerated Fracture Healing Device, #497
- Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures, #498
- Bone Morphogenetic Protein, #097

**Policy**

**Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity**

Noninvasive electrical bone growth stimulation may be **MEDICALLY NECESSARY** as treatment of fracture nonunions or congenital pseudoarthroses in the appendicular skeleton (the appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities). The diagnosis of fracture nonunion must meet **ALL** of the following criteria:
- At least 3 months have passed since the date of fracture, AND
- Serial radiographs have confirmed that no progressive signs of healing have occurred, AND
- The fracture gap is 1 cm or less, AND
- The patient can be adequately immobilized and is of an age likely to comply with non-weight bearing for fractures of the pelvis and lower extremities.

**INVESTIGATIONAL** applications of electrical bone growth stimulation include, but are not limited to, immediate postsurgical treatment after appendicular skeletal surgery, stress fractures, or for the treatment of fresh fractures, delayed union, arthrodesis or failed arthrodesis.

Implantable and semi-invasive electrical bone growth stimulators are **INVESTIGATIONAL.**

**Fresh Fracture**
A fracture is most commonly defined as “fresh” for 7 days after the fracture occurs. Most fresh closed fractures heal without complications with the use of standard fracture care, ie, closed reduction and cast immobilization.
Delayed Union

Delayed union is defined as a decelerating healing process as determined by serial x-rays, together with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than 3 months from the index injury or the most recent intervention.

Nonunion

There is not a consensus for the definition of nonunions. One proposed definition is failure of progression of fracture healing for at least 3 consecutive months (and at least 6 months following the fracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight bearing).¹

The original FDA labeling of fracture nonunions defined nonunions as fractures that had not shown progressive healing after at least 9 months from the original injury. This timeframe is not based on physiologic principles but was included as part of the research design for FDA approval as a means of ensuring homogeneous populations of patients, many of whom were serving as their own controls. Some fractures may show no signs of healing, based on serial radiographs as early as 3 months, while a fracture nonunion may not be diagnosed in others until well after 9 months. The current policy of requiring a 3-month timeframe for lack of progression of healing is consistent with the definition of nonunion as described in the clinical literature.

Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Medical necessity criteria and coding guidance for Medicare Advantage members living in Massachusetts can be found through the link below.

Local Coverage Determination (LCD): Osteogenesis Stimulators (L33796)

For medical necessity criteria and coding guidance for Medicare Advantage members living outside of Massachusetts, please see the Centers for Medicare and Medicaid Services website for information regarding your specific jurisdiction at https://www.cms.gov.

Prior Authorization Information

Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required. Yes indicates that prior authorization is required. No indicates that prior authorization is not required. N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Medical Product</th>
<th>Commercial Managed Care (HMO and POS)</th>
<th>Commercial PPO and Indemnity</th>
<th>Medicare HMO Blue℠</th>
<th>Medicare PPO Blue℠</th>
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<tbody>
<tr>
<td></td>
<td>No</td>
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CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:
CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>20974</td>
<td>Electrical stimulation to aid bone healing; noninvasive (non-operative)</td>
</tr>
<tr>
<td>20975</td>
<td>Electrical stimulation to aid bone healing; invasive (operative)</td>
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HCPCS Codes

<table>
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<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
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<tr>
<td>E0747</td>
<td>Osteogenesis stimulator, electrical, noninvasive, other than spinal applications</td>
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<tr>
<td>E0749</td>
<td>Osteogenesis stimulator, electrical, surgically implanted</td>
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Description

In the appendicular skeleton, electrical stimulation (with either implantable electrodes or noninvasive surface stimulators) has been investigated for the treatment of delayed union, nonunion, and fresh fractures.

Electrical and electromagnetic fields can be generated and applied to bones through the following methods:

- Surgical implantation of a cathode at the fracture site with the production of direct current electrical stimulation. Invasive devices require surgical implantation of a current generator in an intramuscular or subcutaneous space, while an electrode is implanted within the fragments of bone graft at the fusion site. The implantable device typically remains functional for 6 to 9 months after implantation, and, although the current generator is removed in a second surgical procedure when stimulation is completed, the electrode may or may not be removed. Implantable electrodes provide constant stimulation at the nonunion or fracture site but carry increased risks associated with implantable leads.

- Noninvasive electrical bone growth stimulators generate a weak electrical current within the target site using pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. In capacitive coupling, small skin pads/electrodes are placed on either side of the fusion site and worn for 24 hours per day until healing occurs or up to 9 months. In contrast, pulsed electromagnetic fields are delivered via treatment coils that are placed over the skin and are worn for 6–8 hours per day for 3 to 6 months. Combined magnetic fields deliver a time-varying magnetic field by superimposing the time-varying magnetic field onto an additional static magnetic field. This device involves a 30-minute treatment per day for 9 months. Patient compliance may be an issue with externally worn devices.

- Semi-invasive (semi-implantable) stimulators use percutaneous electrodes and an external power supply obviating the need for a surgical procedure to remove the generator when treatment is finished.

In the appendicular skeleton, electrical stimulation has been primarily used to treat tibial fractures, and thus this technique has often been thought of as a treatment of the long bones. According to orthopedic anatomy, the skeleton consists of long bones, short bones, flat bones, and irregular bones. Long bones act as levels to facilitate motion, while short bones function to dissipate concussive forces. Short bones include those composing the carpus and tarsus. Flat bones, such as the scapula or pelvis, provide a broad surface area for attachment of muscles. Despite their anatomic classification, all bones are composed of a combination of cortical and trabecular (also called cancellous) bone. Each bone, depending on its physiologic function, has a different proportion of cancellous to trabecular bone. At a cellular level, however, both bone types are composed of lamellar bone and cannot be distinguished microscopically.

Nonunion

The definition of a fracture nonunion has remained controversial. The original U.S. Food and Drug Administration (FDA) labeling defined nonunion as follows: "A nonunion is considered to be established when a minimum of 9 months has elapsed since injury and the fracture site shows no visibly progressive
signs of healing for minimum of 3 months.” Others have contended that 9 months represents an arbitrary cut-off point that does not reflect the complicated variables that are present in fractures, ie, degree of soft tissue damage, alignment of the bone fragments, vascularity, and quality of the underlying bone stock. Other proposed definitions of nonunion involve 3 to 6 months’ time from original healing, or simply when serial x-rays fail to show any further healing.

**Delayed Union**

Delayed union refers to a decelerating bone healing process, as identified in serial x-rays. (In contrast, nonunion serial x-rays show no evidence of healing.) When lumped together, delayed union and nonunion are sometimes referred to as "ununited fractures."

**Summary**

There is evidence from randomized controlled trials (RCTs) and systematic reviews of clinical trials that noninvasive electrical stimulators improve fracture healing for patients with fracture nonunion. This evidence is not from high-quality RCTs; however, and systematic reviews provide qualified support for this conclusion. Based on the available evidence and the lack of other options for patients with nonunion, electrical stimulation may be considered medically necessary for the U.S. Food and Drug Administration (FDA)-approved indication of fracture nonunions or congenital pseudoarthroses in the appendicular skeleton when specific criteria are met.

There is insufficient evidence to permit conclusions regarding the efficacy of noninvasive electrical bone growth stimulation for treatment of stress fractures or delayed union, or following surgery of the appendicular skeleton. In addition, a recent randomized trial found no benefit of electrical bone growth stimulation for fresh fractures. Use of noninvasive electrical bone growth stimulation for these conditions is considered investigational.

The literature for implantable bone stimulators of the appendicular skeleton consists of a small number of case series. In addition, no semi-invasive devices have FDA clearance or approval. The use of invasive or semi-invasive electrical bone growth stimulators is considered investigational.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>5/2017</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>9/2016</td>
<td>Clarified coding information.</td>
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<tr>
<td>2/2015</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>7/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
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<tr>
<td>12/2013</td>
<td>Removed reference to NCD 150.2 as the LCD for Massachusetts (L11501) meets the intent of the policy. Removed ICD-9 diagnosis codes 966.49, V45.4 as these do not meet the intent of the policy.</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References